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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/625,989

07/24/2003

Kenneth David Reginald Setchell

3515-104

1706

6449

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08/31/2009

ROTHWELL, FIGG, ERNST & MANBECK, P.C.

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SUITE 800

WASHINGTON, DC 20005

EXAMINER

PRYOR, ALTON NATHANIEL

ART UNIT

PAPER NUMBER

1616

NOTIFICATION DATE

DELIVERY MODE

08/31/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/625,989	<b>Applicant(s)</b> SETCHELL ET AL.	
	<b>Examiner</b> ALTON N. PRYOR	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2009 and 30 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7,9-21,25 and 27-36 is/are pending in the application.
- 4a) Of the above claim(s) 6,7,9-21,25,28 and 30-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,29 and 34-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/20/09;7/17/09</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's arguments filed 4/20/09 and 6/30/09 have been fully considered but they are not persuasive. Previous rejections and other issues not addressed below are withdrawn.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,2,4,5,29,34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alvira et al (Molecular modeling study for chiral separation of equol enantiomers by beta-cyclodextrin, vol. 240, issues 1-5, 1999, pp. 101-108). Alvira teaches the separation of R-equol from the S-equol, which meets the limitation of a composition comprising R-equol. Alvira teaches cyclodextrin (carrier) is used in separation process. See reference. Note R-equol is the only required component for the composition claims. Alvira does not teach that the combination of equol and cyclodextrin is pharmaceutical. However, in a claim drawn to a composition a statement to intended use (pharmaceutical) has little patentable significance. In addition, it is well known that cyclodextrin can be used in pharmaceutical compositions which makes it obvious to manufacture the combination of equol and cyclodextrin. Alvira teaches all that is recited in claims 4 and 5 except for the R-equol being present in 90 or 96% enantiomeric purity. An artisan provided the

technique of Alvira would have been able to optimize the purity of R-equol through routine experimentation even to the level of 90 or 96% purity. Alvira teaches all that is recited in claim 29 except for the specified conjugates. In the absence of unexpected data, it would have been obvious to employ any conjugated of the instant equol including those recited in the instant claims. One would have been motivated to do this because equol and conjugates thereof would have been expected to have been equally effective.

*Response to Applicants' argument*

The Applicants argue that the Alvira reference does not disclose or suggest a pharmaceutical composition or any formulation that consist essentially of R-equol plus a pharmaceutical adjuvant, carrier or excipient or any composition comprising pure R-equol or any composition for oral or topical application comprising R-equol which is substantially free of S-equol. Applicants also provide a declaration by Dr. Jackson which demonstrates that R-equol show unexpected results in comparison to the S-equol and racemic in specific applications. The Examiner argues that terms/phrases such as "pharmaceutical composition" and "for oral consumption or topical application" refer to intended use. The Examiner reiterates that in claims drawn to composition a statement to utility has no or little patentable significance. The Examiner further argues that Alvira teaches resolving the R and S isomers of equol in cyclodextrin; therefore, the final composition would consist essentially of R-equol in cyclodextrin which would be substantially free of the S-equol. Although the declaration provides different results for the R-equol with respect to the S-equol and the racemic,

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Alvira has already shown that the R and S isomers of equol are resolvable. For this reason, Alvira reads on instant claims drawn to a composition consisting essentially of R-equol plus cyclodextrin.

**New Rejections based on IDS filed 4/20/09**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Wldyarini et al. (Isoflavonoid compounds from Red Clover (*Trifolium pretense*) Protect from Inflammation and immune Suppression induced by UV Radiation, Photochemistry and Photobiology, 2001, 74(3), pp. 465-470). The reference teaches Isoequol (R-equol) in lotion (carrier). The lotion can be applied topically to treat inflammation (pharmaceutical application). See entire reference.

***Claim Rejections - 35 USC § 103***

Claims 4,5,29,34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wldyarini et al. as applied to claims 1 and 2. See 102 rejection above. The reference teaches all that is recited in claims 4,5,29,34-36 except for the purity level of the R-equol in the composition and the specified conjugates. An artisan provided the teaching of Wldyarini would have been able to optimize the purity of R-equol through routine experimentation even to the level of 90 or 96% purity. In the absence of

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unexpected data, it would have been obvious to employ any conjugated of the instant equol including those recited in the instant claims. One would have been motivated to do this because equol and conjugates thereof would have been expected to have been equally effective.

### ***Telephonic Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alton N. Pryor/  
Primary Examiner, Art Unit 1616

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